

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention**

[60Day-22-22AW; Docket No. CDC-2021-0126]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled *NCEH DLS Laboratory Quality Assurance Programs*. CDC's National Center for Environmental Health (NCEH) Division of Laboratory Science (DLS) provides quality assurance in the form of quality control samples and technical assistance to laboratories to improve analytical accuracy and reliability of tests. Participating laboratories return results to CDC to assess performance.

DATES: CDC must receive written comments on or before [INSERT
DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No.

CDC-2021-0126 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to regulations.gov.

Please note: Submit all comments through the federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed

collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

NCEH DLS Quality Assurance Programs - Existing Collection in Use
Without an OMB Control Number - National Center for
Environmental Health (NCEH), Centers for Disease Control and
Prevention (CDC).

Background and Brief Description

Laboratory Quality Assurance (QA) encompasses a range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods, instrumentation, analytes, source materials, and the volume of specimens tested.

The CDC Division of Laboratory Sciences (DLS) QA programs operate out of multiple laboratories within the division. They establish the baseline measurements and provide calibration and/or quality control (QC) samples that laboratories around the world rely on to develop and improve methods with acceptable levels of accuracy and reliability and, in some cases, meet certain required certifications or accreditation. Laboratories use DLS-developed samples to test the quality and accuracy of their methods/assays. Participating laboratories enroll in the DLS QA program that fits their needs (i.e., external quality assurance/performance assessment, proficiency testing, accuracy-based monitoring, or standardization/harmonization). After the laboratories receive DLS QA samples and perform their

measurements, they return test results to DLS. DLS then evaluates the data using statistical methods and reports back to the laboratories on their analytical performance. Laboratories may receive additional technical assistance (TA)/troubleshooting to improve their method performance as needed. DLS programs are offered at different frequencies.

There are 13 DLS QA programs conducted by the following five DLS branches. These programs provide materials and test result analysis to laboratories for the purpose of improving and/or standardizing test performance.

- Clinical Chemistry Branch (CCB)
 - Accuracy-based Laboratory Monitoring Programs (AMP)
 - Lipid Standardization Program (LSP) for Clinical Biomarkers
 - Cholesterol Reference Method Laboratory Network (CRMLN)
 - Hormone Standardization (HoST) Program
 - Vitamin D Standardization Certification Program (VDSCP)
- Nutrition Biomarkers Branch (NBB)
 - Vitamin A Laboratory - External Quality Assurance (VITAL-EQA)
 - Quality Assurance Method Performance Verification (MPV) for Folate Microbiologic Assay (MBA)
 - Quality Assurance Method Performance Verification (MPV) for Micronutrients

- Organic Analytical Toxicology Branch (OATB)
 - Biomonitoring Quality Assurance Support Program (BQASP)
- Inorganic Radiation and Analytical Toxicology Branch (IRATB)
 - Proficiency in Arsenic Speciation (PAsS) Program
 - Ensuring the Quality of Urinary Iodine Procedures (EQUIP)
 - Lead and Multielement Proficiency (LAMP) Testing Program
- Newborn Screening and Molecular Biology Branch (NSMBB)
 - Newborn Screening and Quality Assurance Program (NSQAP)

All 13 CDC QA programs help improve the accuracy and reliability of tests performed by laboratories in patient care, research, commercial and public health settings. They also help to make measurement results among research studies and among clinical laboratories more comparable. Collectively, these programs improve the quality of laboratory tests that measure environmental exposures and chronic disease biomarkers (including nutritional indicators and hormones) to better inform critical patient care and public health decisions for an expansive host of health outcomes such as rare heritable disorders in newborns, endocrine disorders, maternal health and risk of birth defects, bone, kidney and cardiovascular disease,

cancers (including breast cancer), diabetes, and thyroid and hormone dysregulation.

The estimated annualized burden hours were determined as follows. There are 1,720 participating laboratories across the 13 DLS QA programs. A "respondent" refers to a single laboratory represented by an individual laboratory analyst who would record the data from their testing results in the supplied data submission form(s). Depending on the program, the average burden per response for the enrollment and data submission forms was determined to be five minutes up to two hours through firsthand experience in testing usability/data entry of forms. The number of respondents fluctuates minimally each year and an average number of participants per program was estimated by each program based on previous years' participation and trends in participation rate since the inception of each program. CDC has estimated the annualized burden for these 13 programs to be 4,293 hours per year.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
CCB Accuracy-based Laboratory Monitoring Programs (AMP)					
Academic/ University Research Lab	AMP Enrollment and Data Submission Form	10	1	25/60	4

	AMP Enrollment and Data Submission Form	10	4	45/60	30
Private Research Lab	AMP Enrollment and Data Submission Form	3	1	25/60	1
	AMP Enrollment and Data Submission Form	3	4	45/60	9
Routine Clinical Lab	AMP Enrollment and Data Submission Form	20	1	25/60	8
	AMP Enrollment and Data Submission Form	20	4	45/60	60
CCB Lipid Standardization Program (LSP)					
Academic/ University Research Lab	LSP Enrollment and Data Submission Form	20	1	25/60	8
	LSP Enrollment and Data Submission Form	20	4	45/60	60
Private Research Lab	LSP Enrollment and Data Submission Form	7	1	25/60	3
	LSP Enrollment and Data Submission Form	7	4	45/60	21
Routine Clinical Lab	LSP Enrollment and Data Submission Form	40	1	25/60	17

	LSP Enrollment and Data Submission Form	40	4	45/60	120
CCB Cholesterol Reference Method Laboratory Network (CRMLN)					
CRMLN Network Laboratories	CRMLN Enrollment Email	15	1	10/60	3
	CRMLN Data Submission Form	15	2	2	60
CCB Hormone Standardization (HoSt) Program					
Assay Manufacturers	HoSt Enrollment and Data Submission Form	60	1	30/60	30
	HoSt Enrollment and Data Submission Form	60	4	1	240
Lab Developed Tests (LDT) Manufacturers	HoSt Enrollment and Data Submission Form	40	1	30/60	20
	HoSt Enrollment and Data Submission Form	40	4	1	160
End-user/Labs	HoSt Enrollment and Data Submission Form	20	1	30/60	10
	HoSt Enrollment and Data Submission Form	20	4	1	80
CCB Vitamin D Standardization Certification Program (VDSCP)					
Assay Manufacturers	VDSCP Enrollment and Data Submission Form	60	1	30/60	30
	VDSCP Enrollment and Data	60	4	1	240

	Submission Form				
LDT Manufacturers	VDSCP Enrollment and Data Submission Form	40	1	30/60	20
	VDSCP Enrollment and Data Submission Form	40	4	1	160
End-user/ Labs	VDSCP Enrollment and Data Submission Form	20	1	30/60	10
	VDSCP Enrollment and Data Submission Form	20	4	1	80
NBB Vitamin A Laboratory – External Quality Assurance (VITAL-EQA)					
Academic/ University Research Lab	VITAL-EQA Enrollment Form	30	1	25/60	13
	Data Submission Form	30	2	45/60	45
Government / Ministry of Health Lab	VITAL-EQA Enrollment Form International	30	1	25/60	13
	Data Submission Form	30	2	45/60	45
Private Research Lab	VITAL-EQA Enrollment Form	15	1	25/60	6
	Data Submission Form	15	2	45/60	23
Clinical Lab	VITAL-EQA Enrollment Form	15	1	25/60	6
	Data Submission Form	15	2	45/60	23
NBB Quality Assurance Method Performance Verification (MPV) for Folate Microbiologic Assay (MBA)					

Academic/ University Research Lab	MPV Folate MBA Enrollment and Data Submission Form	15	1	25/60	6
	MPV Folate MBA Enrollment and Data Submission Form	15	4	45/60	45
Government / Ministry of Health Lab	MPV Folate MBA Enrollment and Data Submission Form	15	1	25/60	6
	MPV Folate MBA Enrollment and Data Submission Form	15	4	45/60	45
Private Research Lab	MPV Folate MBA Enrollment and Data Submission Form	5	1	25/60	2
	MPV Folate MBA Enrollment and Data Submission Form	5	4	45/60	15
Clinical Public Health Lab	MPV Folate MBA Enrollment and Data Submission Form	5	1	25/60	2
	MPV Folate MBA Enrollment and Data Submission Form	5	4	45/60	15
NBB Quality Assurance Method Performance Verification (MPV) for Micronutrients					
Academic/ University	MPV Micronutrien	20	1	25/60	8

Research Lab	ts Enrollment and Data Submission Form				
	MPV Micronutrients Enrollment and Data Submission Form	20	4	45/60	60
Government / Ministry of Health Lab	MPV Micronutrients Enrollment and Data Submission Form	20	1	25/60	8
	MPV Micronutrients Enrollment and Data Submission Form	20	4	45/60	60
Private Research Lab	MPV Micronutrients Enrollment and Data Submission Form	10	1	25/60	4
	MPV Micronutrients Enrollment and Data Submission Form	10	4	45/60	30
Clinical Public Health Lab	MPV Micronutrients Enrollment and Data Submission Form	10	1	25/60	4
	MPV Micronutrients Enrollment and Data	10	4	45/60	30

	Submission Form				
OATB Biomonitoring Quality Assurance Support Program (BQASP)					
State Public Health Labs	BQASP Enrollment Email	10	1	5/60	1
	BQASP Data Submission Form	10	1	45/60	8
IRATB Proficiency in Arsenic Speciation (PAsS) Program					
Public Health Labs	PAsS Enrollment Form	28	1	10/60	5
	PAsS Data Submission Form	28	4	10/60	19
IRATB Ensuring the Quality of Urinary Iodine Procedures (EQUIP)					
Public Health Labs	EQUIP Enrollment Form	240	1	10/60	41
	EQUIP Data Submission Form	240	3	10/60	122
IRATB Lead and Multielement Proficiency (LAMP) Testing Program					
Public Health Labs	LAMP Enrollment Form	226	1	10/60	39
	LAMP Data Submission Form	226	4	10/60	154
NSMBB Newborn Screening and Quality Assurance Program (NSQAP)					
Domestic NBS Labs	NSQAP Enrollment Form	71	1	10/60	12
	NSQAP Data Submission Portal Quality Control (QC)	71	2	45/60	107
	NSQAP Data Submission Portal Biochemical & Molecular Proficiency Tests (PT)	71	3	45/60	160
International NBS Labs	NSQAP Enrollment Form	568	1	10/60	95
	NSQAP Data Submission Portal QC	568	2	45/60	129

	NSQAP Data Submission Portal Biochemical & Molecular PT	568	3	45/60	1,278
NBS Test Manufacturers	NSQAP Enrollment Form	32	1	10/60	5
	NSQAP Data Submission Portal QC	32	2	45/60	48
	NSQAP Data Submission Portal Biochemical & Molecular PT	32	3	45/60	72
Total		1,720			4,293

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